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(71) Applicants *(for all designated States except US)*: **EDWARDS LIFESCIENCES CORPORATION** [US/US]; One Edwards Way, Irvine, CA 92625 (US). **ENDOGAD RESEARCH PTY LIMITED** [AU/AU]; P.O. Box M88, Camperdown, NSW 2050 (AU).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DEHDASHTIAN, Mark** [US/US]; 1696 Palau Place, Costa Mesa, CA 92626 (US). **WHITE, Geoffrey, H.** [AU/AU]; 22 Nicholson Street, East Balmain, NSW 2041 (AU). **YU, Weiyun** [AU/AU]; Apt.59 #8, Birchgrove, NSW 2041 (AU).

(74) Agents: **GLUCK, Peter, J.** et al.; Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614 (US).

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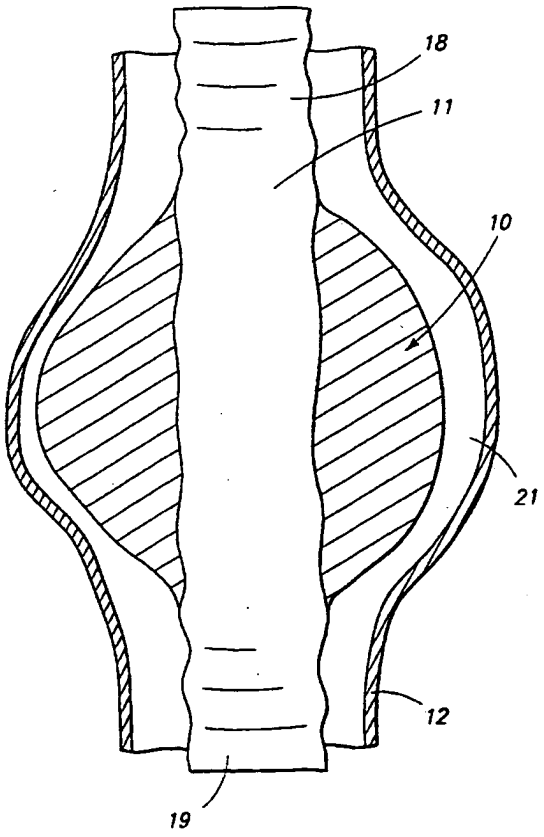


(57) Abstract: An implant adapted to be inserted into a vessel of a patient suffering from at least one of aneurysmal disease and stneotic, the implant being expandable such that when positioned within the vessel it substantially fills the aneurysmal disease, the implant further being expandable such that when positioned within the vessel it substantially fills the aneurysmal sac of the vessel and having a surface, the surface being adapted to abut with an intraluminal graft inserted into the vessel, among other ways of facilitating exclusion or ameliorative reduction of such disease states.

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# IMPLANTS FOR THE USE IN THE TREATMENT OF ANEURYSMS

This application claims all Paris Convention Priority rights from Australian Provisional Patent Application No. PQ3028, filed 23 September 1999.

## Field of the Invention

The present invention relates to an implant for the use in the treatment of aneurysmal disease, the implant providing support for an intraluminal graft whilst also enhancing thrombosis in the aneurysmal sac, cellular reaction to and infiltration into the intraluminal graft and fibrosis or similar hardening within the aneurysmal sac.

## Background Art

Conventional treatment of aneurysmal disease involves the introduction of a graft into a vessel with a view to bypassing the aneurysm. Grafts are typically introduced into the affected vessel through a distal (or proximal) and connecting vessel to that in which the device is to be used. For example, in cases where the graft is to be used to by-pass an aneurysm in the aorta the graft may be inserted in a catheter through the femoral artery.

Once secured in place within the vessel, any flow of blood to the surrounding aneurysmal sac is prevented. There may, however, still be a substantial volume of blood present in the by-passed aneurysmal sac. This blood subsequently undergoes clotting by way of a natural process known as thrombosis. The contents of the aneurysmal sac subsequently undergo a further process known as fibrosis, which results in the hardening of the contents. In this way, the aneurysm starts to shrink and the cells surrounding the intraluminal graft start to adhere and infiltrate the intraluminal graft. The overall result is that the intraluminal graft is embedded in the surrounding tissue and thus further secured in place within the vessel.

The above described processes are natural processes which take time to occur and thus in the early stages of graft implantation, there is no additional support of the graft by the surrounding tissue. When it is considered that often a graft will dislodge during this early stage, it would be desirable to provide a means for additionally supporting the graft upon placement in a vessel whilst also stimulating and enhancing the natural process of thrombosis, fibrosis and cellular adhesion the graft.

**Disclosure of the Invention**

In a first aspect, the present invention provides an implant adapted to be inserted into a vessel of a patient suffering from aneurysmal disease, the implant being expandable such that when positioned within the vessel it substantially fills the aneurysmal disease, the implant being expandable such that when positioned within the vessel it substantially fills the aneurysmal sac of the vessel and having a surface, the surface being adapted to abut with an intraluminal graft inserted into the vessel.

In one embodiment of the first aspect of the present invention, the implant includes a tubular wall surrounding an internal passage, the passage being adapted to receive an intraluminal graft inserted therein.

In a second aspect, the present invention provides an intraluminal device adapted to be inserted into a vessel of a patient suffering from aneurysmal disease, the intraluminal device including a tubular graft body having a length and a first and at least second end and an implant disposed around at least a portion of the tubular body wherein when in situ, the implant expands to substantially fill the aneurysmal sac of the vessel in which the device is placed.

In one embodiment of the second aspect of this invention, the implant is attached to a portion of the tubular graft body.

In a still further embodiment of the second aspect of this invention, the implant is attached to a portion of the tubular graft body.

In a third aspect, the present invention provides a method for positioning an implant in a vessel of a patient suffering from aneurysmal disease, the implant having a tubular wall surrounding an internal passage, the method including the steps of introducing a catheter into the vessel, causing the implant to be moved through the catheter in a compressed state until it extends into the vessel from the proximal end of the catheter wherein when extended from the proximal end of the catheter, the implant moves from its compressed state to an expanded state within the vessel such that the implant expands to substantially fill the aneurysmal sac of the vessel in which it is disposed.

In one embodiment, once the implant is in situ within the vessel, an intraluminal device is inserted into the vessel such that when in situ, the intraluminal device is positioned internal the implant. In preferred embodiments, the walls of the intraluminal device may be inserted into the vessel as a first step and the implant inserted thereafter such that the implant is positioned external the intraluminal device, the implant expanding to fill the aneurysmal sac within which it is disposed.

In a fourth aspect, the present invention provides a method for positioning an intraluminal device within the vessel of a patient suffering from aneurysmal disease wherein the intraluminal graft body includes a tubular graft body having a length and a first and at least second end and an implant disposed around at least a portion of the wall of the tubular graft body, the method including the steps of introducing a catheter into the body, the method including the steps of introducing a catheter into the vessel, causing the intraluminal device to be moved through the catheter in a vessel, causing the intraluminal device to be moved through the catheter in a compressed state until it extends from the proximal end of the catheter wherein when extended from the proximal end of the catheter, the intraluminal device moves from its compressed state to an expanded state such that the implant expands to

substantially fill the aneurysmal sac of the vessel in which the intraluminal device is disposed.

In another embodiment of the invention, the material of the implant may be naturally resilient such that it will spring back into shape as soon as a compressive pressure has been removed.

In a further embodiment, the implant may be formed from a foam or sponge material.

In still a further embodiment, the implant is formed of a polymer sponge.

In yet a further embodiment, the implant is formed of a naturally resilient material that has an expansion ratio of from 1.5:1 up to 50:1.

In another embodiment, the implant may be made from a resorbable material such as a resorbable polymer or polycarbonate/polyurethane composite foam or sponge material. It may however be made entirely of a non-resorbable material. It may however be made entirely of non-resorbable material provided that it is bio-compatible and will not set up an inflammatory, or other, reaction in the patient. In one embodiment, the implant is made from polyurethane alone.

In a further embodiment, the implant may be inflatable such that it is inserted in its deflated configuration. Once in situ within the vessel in which it is disposed, fluid may be pumped into the implant such that it takes on its inflated configuration.

In another embodiment, the implant is made from an injectable material such as injectable foam. In this embodiment, the implant may have particular application in instances where an aneurysm has burst, In this case, the implant can be injected into the aneurysm such that it takes on the shape of the aneurysm before it burst. In a preferred form, the implant is made from a material adapted to harden when in situ within the vessel. An intraluminal device may be inserted internal the implant and pushed through the hardening material.

In another embodiment, the implant may contain within its structure, metallic wire or wireforms. In the case of non-resorbable tubular member these wires may be a permanent part of the implant.

In one embodiment of the invention these wires may be formed of Nitinol or another material that will change shape at the temperature of blood. In this way the wires could be designed to change shape such that when positioned within a vessel of a patient, the implant expands into and substantially fills an aneurysmal sac of a vessel within which it is disposed.

In a further embodiment of the invention, the material of the implant may be pre-treated with a suitable bioactive, pharmacological or genetically active material to enhance aneurysmal thrombosis, cellular reaction and adhesion to the intraluminal graft fibrosis or hardening within the aneurysmal sac.

In one embodiment, the material of the implant is a biodegradable polymer with thrombogenic properties.

In a further embodiment of the present invention the implant may be used in the treatment of aortic aneurysms. In addition to treating aortic aneurysms the implant is also suitable for treating aneurysms of the femoral artery, the popliteal artery, the thoracic segment of the aorta, visceral arteries such as the renal and mesenteric arteries, the iliac artery and the sub-clavian artery.

In another embodiment, the implant may be pre-shaped such that it first within an aneurysmal sac of a patient In this manner, an image may be made of the aneurysm (i.e. by ultrasound) and the implant custom to fit securely within the aneurysm.

In a further embodiment, the implant is made from a plurality of separate portions. It is envisaged that this embodiment could be used in the case where an aneurysm span the bifurcation of an artery, for example, the aorta-iliac junction. In such a cases, a first portion of the implant could be positioned in the aortic region of

the aneurysmal sac and a second portion positioned in the iliac region of the aneurysmal sac, inferior the bifurcation of the aorta.

In one embodiment of the second and fourth aspects of the present invention, the tubular graft body of the intraluminal device is preferably formed of a thin biocompatible material such as Dacron™ or polytetrafluoroethylene (PTFE). The tuber material is preferably crimped along its length to increase the device's flexibility, however uncrimped material may be used in suitable circumstances.

In addition, in a further preferred embodiment the tubular graft body of the second and fourth aspects of the invention includes a stent or a series of spaced apart stents which forms a framework to which may be attached an endoluminal graft. The framework of the tubular graft body may be circumferentially reinforced along its length by a plurality of separate, spaced-apart, malleable wires. Each of such wires can have a generally closed sinusoidal or zigzag shape. The wires are preferable formed of stainless steel or another metal of a plastic, which is malleable and is biocompatible. Each wire is preferably woven into the fabric of the device body to integrate the body and the reinforcing wires. This prevents any possibility of the wire reinforcement separating from the device body during introduction of the tubular graft body or throughout its life. If the tubular graft body is of a woven material the wires may be interwoven with the tubular graft body after manufacture. If the tubular graft body is not woven but is knitted or of an impervious sheet material then the wires may be threaded through suitable holes formed in the tubular graft body. Alternatively the stent or stents may be continuous and may be on the radially inner of the radially outer side of the graft wall.

In a still further embodiment of the second and fourth aspects, the tubular graft body is typically substantially of constant diameter along its length, that is, it is substantially cylindrical or may in some instances be frusto-conical in shape with a diameter that increases or decreases along the length of the device.

In another embodiment, the device of aspects two and four of the invention is adapted to bridge the aneurysm that extends up to or slightly beyond an arterial bifurcation. In such a case the device includes a tubular graft body which has a bifurcation at its downstream end, a so-called :trouser graft", and may be placed wholly within the primary artery. A supplemental graft may then be introduced through subsidiary arteries and overlapped with the lumen of the bifurcated part of the primary graft. In the cases of an aneurysm in the aorta, for instance, that extended into each of the common iliac arteries the primary graft would be placed in the aorta. Supplemental grafts which dock with the bifurcated end of the primary graft would then be inserted through each of the common iliac arteries.

**Brief Description of the Drawings**

Herein after by way of example is a preferred embodiment of the present invention with reference to the accompanying drawings, in which:

Figure 1 is a longitudinal section view of an aortic aneurysm within which one embodiment of the present invention has been inserted.

Figure 2 is a diagrammatic partially cut away ventral view of a patient with an aortic aneurysm which has been bridged by one embodiment of the present invention.

Figure 3 is a diagrammatic view of an aneurysm located in the region of the bifurcation of the aorta, the aneurysm having been bridged by one embodiment of the present invention.

**Best Mode of Carrying out the Invention**

An implant of the present invention is generally shown as 10 in the drawings. The implant 10 is adapted for insertion transfemorally with an intraluminal graft 11. It is to be understood, however, that the implant 10 may also be inserted independently of the intraluminal graft 11.

As is shown in Figure 2, the aorta 12 bifurcates to form the common iliac arteries 13 which subsequently divide into the external 14 and internal 15 iliac arteries, the external iliac artery 14 eventually becoming the femoral artery 16. The aortic aneurysm is located between the renal arteries 17 and the junctions of the bifurcation of the aorta 12 into the common iliac arteries 13.

In the embodiment of the invention depicted in the drawings, the implant 10 is attached to an intraluminal graft 11 along a substantial portion of the length of the intraluminal graft 11. Both the implant and the intraluminal graft are packaged into a catheter (not shown) and introduced into one of the femoral arteries 16. Once the catheter is located approximately which its proximal end in the aorta 12, the implant 10 and intraluminal graft 11 are ejected from the catheter and expanded so that each end 18 and 19 of the intraluminal graft is in intimate contact around its full periphery with the aorta 12 and the implant 10 expands to substantially fill the aneurysmal sac 21.

In the embodiment of the invention depicted in Figure 3, the implant 10 comprises three individual segments. This embodiment is adapted such that it may be used in respect of an aneurysm spanning the area of the aorta 12 that bifurcates to form the common iliac arteries 13. The portions of the implant may be attached to an intraluminal graft 11 of may be inserted into the distinct areas of the aneurysm separately.

It will be appreciated by persons skilled in the art of numerous variations and/or modification may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and non-restrictive.

**In The Claims:**

1. An endovascular implant adapted to be inserted into a vessel of a patient suffering from aneurysmal disease, the implant being expandable such that when positioned within the vessel it substantially fills the aneurysmal disease, the implant being expandable such that when positioned within the vessel it substantially fills the aneurysmal sac of the vessel and having a surface, the surface being adapted to abut with an intraluminal graft inserted into the vessel.

2. Implant as defined in claim 1, further comprising:
a tubular wall surrounding an internal passage, the passage being adapted to receive an intraluminal graft inserted therein.

3. Implant as defined in claim 1, further comprising:
a tubular graft body having a length and a first and at least second end and an implant disposed around at least a portion of the tubular body wherein when in situ, the implant expands to substantially fill the aneurysmal sac of the vessel in which the device is placed.

4. Implant as defined in claim 3, wherein said implant is attached to a portion of the tubular graft body.

5. A method for positioning an implant in a vessel of a patient suffering from aneurysmal disease, the implant having a tubular wall surrounding an internal passage, the method including the steps of introducing a catheter into the vessel, causing the implant to be moved through the catheter in a compressed state until it extends into the vessel from the proximal end of the catheter wherein when extended from the proximal end of the catheter, the implant moves from its compressed state

to an expanded state within the vessel such that the implant expands to substantially fill the aneurysmal sac of the vessel in which it is disposed.

6. Method as defined in claim 5, wherein the walls of the intraluminal device may be inserted into the vessel as a first step and the implant inserted thereafter such that the implant is positioned external the intraluminal device, the implant expanding to fill the aneurysmal sac within which it is disposed.

7. A method for positioning an intraluminal device within the vessel of a patient suffering from aneurysmal disease wherein the intraluminal graft body includes a tubular graft body having a length and a first and at least second end and an implant disposed around at least a portion of the wall of the tubular graft body, the method comprising:
introducing a catheter into the vessel,
causing the intraluminal device to be moved through the catheter in a vessel, in a compressed state until it extends from the proximal end of the catheter wherein when extended from the proximal end of the catheter, the intraluminal device moves from its compressed state to an expanded state such that the implant expands to substantially fill the aneurysmal sac of the vessel in which the intraluminal device is disposed.

8. Implant as defined in claim 1, further comprising:
at least a portion of the material of the implant being naturally resilient such that it will spring back into shape as soon as a compressive pressure has been removed.

9. Implant as defined in claim 8, further comprising a foam or sponge material.

10. Implant as defined in claim 8, further comprising a polymer sponge.

11. Implant as defined in claim 8, further comprising at least one naturally resilient material selected from the group consisting of those having an expansion ratio of from about 1.5:1 to about 50:1.

12. Implant as defined in claim 8, further comprising at least one bio-compatible resorbable material selected from the group consisting of resorbable polymers, polycarbonate/polyurethane composite foams and sponge material.

13. Implant as defined in claim 8, consisting essentially of polyurethane .

14. Implant as defined in claim 8, whereby said implant is inflatable such that it is inserted in its deflated configuration and in situ within the vessel in which it is disposed, fluid may be pumped into the implant such that it takes on its inflated configuration.

15. Implant as defined in claim 8, wherein said implant is made from an injectable material such as injectable foam.

16. Implant as defined in claim 15, effective for use in instances where an aneurysm has burst such that it takes on the shape of the aneurysm before it burst.

17. Implant as defined in claim 16, wherein the implant is made from a material adapted to harden when in situ within the vessel whereby an intraluminal device may be inserted internal the implant and pushed through the hardening material.

18. Implant as defined in claim 8, further comprising metallic wire or wireforms wherein for non-resorbable tubular members said wires are a permanent part of the implant.

19. Implant as defined in claim 18, further comprising Nitinol or another material that will change shape at the temperature of blood whereby said change shape such that when positioned within a vessel of a patient, the implant expands into and substantially fills an aneuyismal sac of a vessel within which it is disposed.

20. Implant as defined in claim 18, further comprising material of the implant being pre-treated with a suitable bioactive, pharmacological or genetically active material to enhance aneurysmal thrombosis, cellular reaction and adhesion to the intraluminal graft fibrosis or hardening within the aneurysmal sac.

21. Implant as defined in claim 18, further comprising at least a biodegradable polymer with thrombogenic properties.

22. Implant as defined in claim 21, effective for use with at least one aneurysm selected from the group consisting of aortic aneurysms, aneurysms of the femoral artery, the popliteal artery, the thoracic segment of the aorta, visceral arteries such as the renal and mesenteric arteries, the iliac artery and the sub-clavian artery.

23. Implant as defined in claim 22, whereby said implant is pre-shaped such that it first within an aneurysmal sac of an image may be made of the aneurysm (i.e. by ultrasound) and the implant custom to fit securely within the aneurysm.

24. Implant as defined in claim 23, wherein said implant is made from a plurality of separate portions.

25. Implant as defined in claim 24, formed of at least one thin biocompatible material sleected from the group consisting of Dacron™ and polytetrafluoroethylene (PTFE) and is preferably crimped along its length to increase the device's flexibility.

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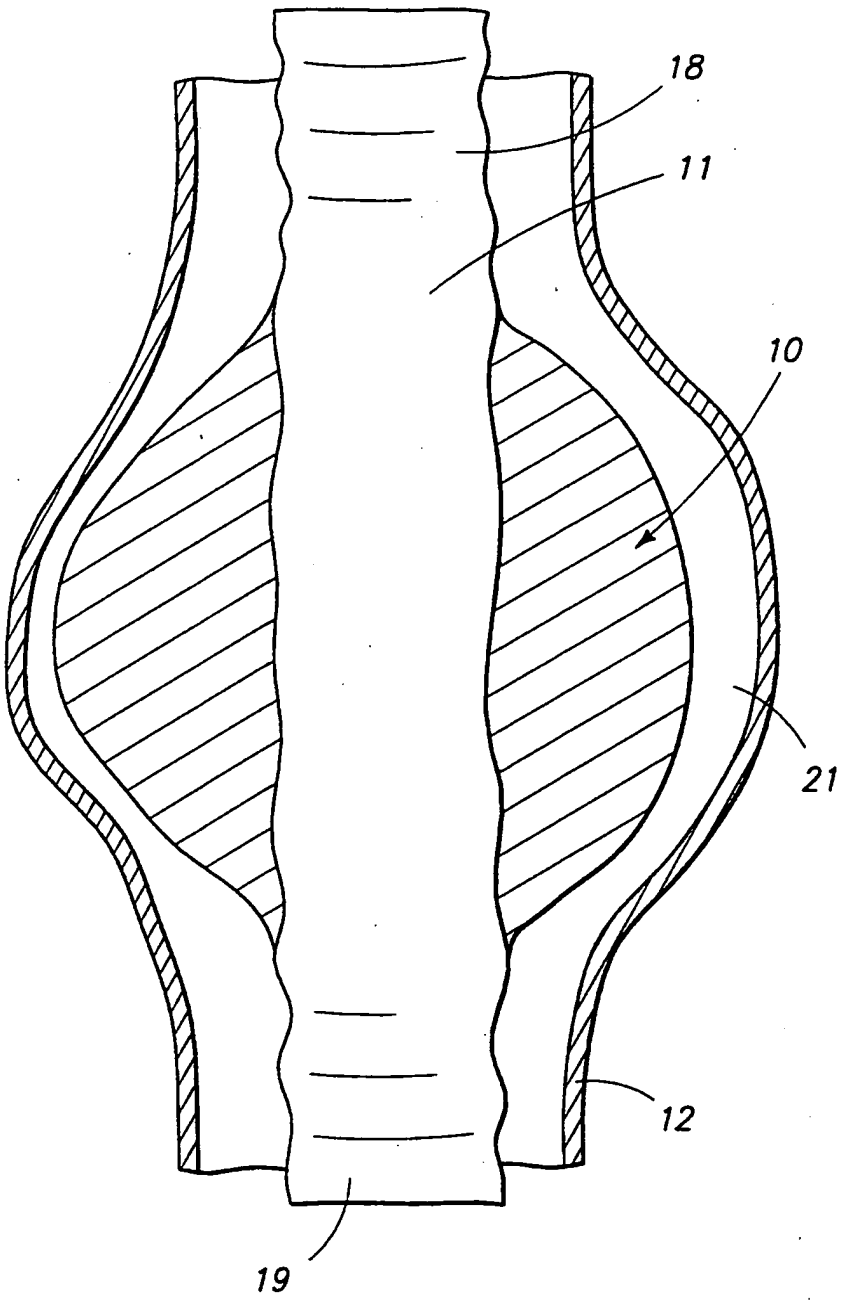


FIG. 1

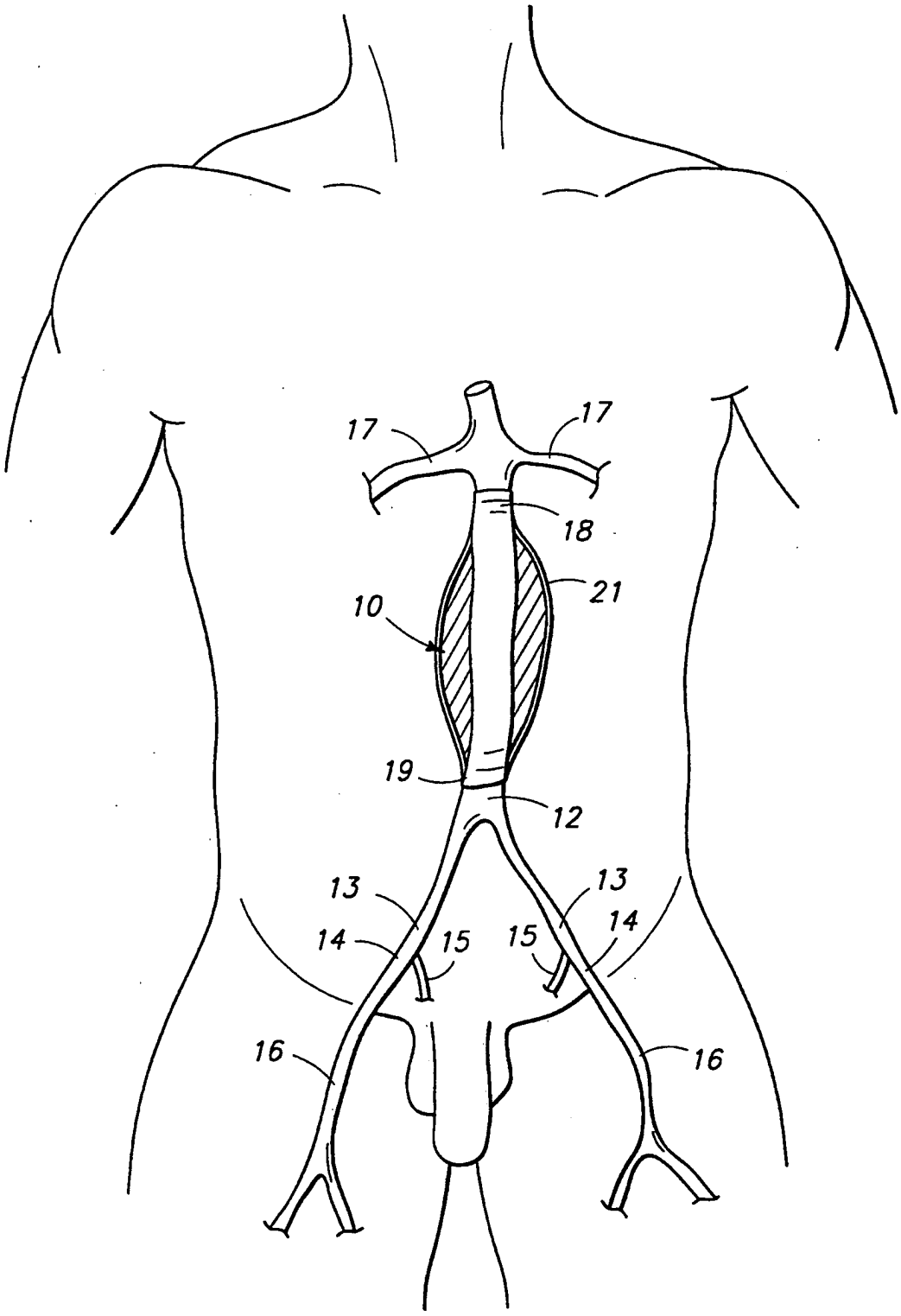


FIG. 2

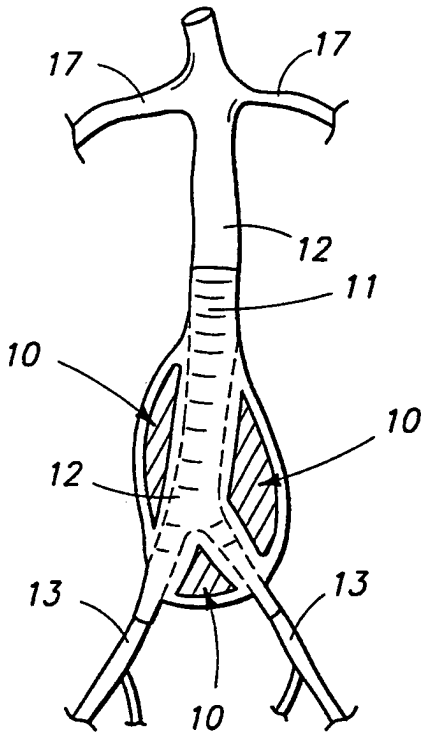


FIG. 3

# INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/US 00/26333

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>Y | WO 97 19653 A (RHODES)<br>5 June 1997 (1997-06-05)<br>the whole document | 1-4<br>8-11,13,<br>14,16,18 |
| Y | WO 99 23954 A (SALVIAC LIMITED)<br>20 May 1999 (1999-05-20)<br>the whole document | 8-11,13,<br>14,16,18 |
| A | WO 98 41167 A (SPOELSTRA)<br>24 September 1998 (1998-09-24)<br>abstract; figures | 1 |
| A | WO 97 03717 A (ENDOTEX INTERVENTIONAL SYSTEMS, INC.)<br>6 February 1997 (1997-02-06)<br>abstract; figures | 1 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
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| 3 January 2001 | 11/01/2001 |

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ional Application No
PCT/US 00/26333

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